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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/131,385 08/07/98 STELLA V 1257-0116P

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EXAMINER
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ART UNIT	PAPER NUMBER
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1612

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DATE MAILED:

10/21/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/131,385

Applicant(s)

Stella, V.J. et al.

Examiner  
Charanjit Aulakh

Group Art Unit  
1612



☒ Responsive to communication(s) filed on Aug 30, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-5, 8-12, and 16-31 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☒ Claim(s) 25, 26, 28, and 29 is/are allowed.

☒ Claim(s) 16-24, 30, and 31 is/are rejected.

☒ Claim(s) 1-5, 8-12, and 27 is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

1. According to paper no. 6, filed on Aug. 30, 1999, the applicants have amended claim 16 and furthermore, have added new claims 19-31.
2. Claims 1-5, 8-12 and 16-31 are now pending in the application.

### ***Response to Arguments***

3. Applicant's arguments filed on Aug. 30, 1999 ( paper no. 6 ) have been fully considered but they are not persuasive regarding restriction requirement and indefiniteness rejection.

In regard to restriction requirement, the examiner does not agree with the applicants arguments on page 3 that the common core is represented by phosphonooxymethyl group in the instant claims because [R] is so diverse in scope that a prior art reference anticipating the claims under 35 U.S.C. 102(b) with respect to one member would not render obvious the same claim under 35 U.S.C. 103(a) with respect to another member. Further, the prodrug precursors represent independent and distinct structures. No reasonable assurance that these different structures can be cleaved by the human or animal body and function as precursors without objective evidence. Also, as stated in paper no. 4, the compounds are classified in different classes and subclasses based on the value of R variable and therefore, constitutes a burdensome search. Therefore, restriction requirement as indicated is proper.

In regard to indefiniteness rejection of claim 16, the amendment to claim 16 still does not overcome this rejection since claims 16-22 are still directed to improper product use claims.

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Regarding prior art rejections under 35 U.S.C. 102(b), the examiner agrees with the applicants arguments on page 4 that compounds cited in either Cho's reference or Varia's reference do not contain additional (-O-)n linkage. The examiner also agrees with the applicants arguments on page 5 that Bundgaard teaches modification of poorly soluble drug to a direct phosphate ester whereas the instant claims are directed to indirect phosphate ester and furthermore, showing of superior activity of instant prodrug as compared to direct phosphate ester method ( submitted as declaration ) was convincing.

#### ***Conclusion***

4. Rejection of claims 1 and 3 under 35 U.S.C. 102(b) over either Cho or Varia is now withdrawn.
5. Rejection of claims 1-5, 8-12 and 16-18 under 35 U.S.C. 103(a) is now withdrawn.
6. Rejection of claims 16-22 under 35 U.S.C. 112, second paragraph is maintained since the claims are directed to improper product use claims; see *Clinical Products Ltd. V. Brenner*, 255 F. Suppl.131, 149 USPQ 475 ( D.D.C. 1966 ).

#### **NEW GROUNDS OF REJECTION**

#### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 23, 24, 30 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23, 24, 30 and 31 are indefinite since there is no formula I present in claim 23 and furthermore, variables R1 and R2 are not defined.

9. Claims 1-5, 8-12 and 16-22 are objected to as being directed to Improper Markush Group since there is no common core present which is essential to the utility. The applicants are suggested to amend claims to read upon the elected group to overcome this objection.

***Allowable Subject Matter***

10. Claim 27 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

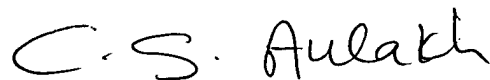
11. Claims 25, 26, 28 and 29 are allowed since the instant propofol prodrugs are neither disclosed nor obvious over the prior art. In the prior art, Golik ( EP 0 604 910, cited on applicants form 1449 ) discloses phosphonooxymethyl prodrugs of taxane derivatives. However, there is no motivation or suggestion to use phosphonooxymethyl moiety to prepare prodrugs of propofol.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chana Aulakh whose telephone number is (703) 305-4482. The examiner can normally be reached on " Monday-Thursday " from 7:30 A.M. to 6:00 P.M.

If the attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. John Kight, can be reached on (703) 308-0204. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's receptionist whose telephone number is (703) 308-1235.



CHARANJIT S. AULAKH

ASSISTANT EXAMINER